

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG
MDL No. 2738**

THIS DOCUMENT RELATES TO ALL CASES

CERTIFICATION OF MICHELLE A. PARFITT, ESQ.

Michelle A. Parfitt, Esq., hereby certifies as follows:

1. I am an attorney at law and member of the law firm of Ashcraft & Gerel, LLP. I was appointed as Co-Lead Counsel to represent all Plaintiffs in the above-captioned matter.
2. I submit this Certification based on personal knowledge in support of the PSC's Omnibus Memorandum of Law in Response and Opposition to Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Plaintiffs' General Causation Opinions.
3. Attached hereto as Exhibit 1 is a true and correct copy of A.B. Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965).
4. Attached hereto as Exhibit 2 is a true and correct copy of the Expert Report of Anne McTiernan, MD, Ph.D, dated November 16, 2018.

5. Attached hereto as Exhibit 3 is a true and correct copy of the Testimony of Anne McTiernan before the House of Representatives Subcommittee on Economic and Consumer Policy, dated March 12, 2019.

6. Attached hereto as Exhibit 4 is a true and correct copy of the Expert Report of Jack Siemiatycki, MSc, PhD, dated November 16, 2018.

7. Attached hereto as Exhibit 5 is a true and correct copy of Langseth, et al., *Perineal Use of Talc and Risk of Ovarian Cancer*, 62 J. Epidemiology Comm. Health 358 (2008).

8. Attached hereto as Exhibit 6 is a true and correct copy of the Expert Report of Patricia G. Moorman, MSPH, Ph.D., dated November 16, 2018.

9. Attached hereto as Exhibit 7 is a true and correct copy of the Deposition of Patricia G. Moorman, MSPH, Ph.D., dated January 25, 2019.

10. Attached hereto as Exhibit 8 is a true and correct copy of Schildkraut, et al., *Association Between Body Powder Use and Ovarian Cancer: The African American Epidemiology Study (AACES)*, 25 Cancer Epidemiology Biomarkers Prev. 1411(2016).

11. Attached hereto as Exhibit 9 is a true and correct copy of the Expert Report of Rebecca Smith-Bindman, M.D., dated November 16, 2018.

12. Attached hereto as Exhibit 10 is a true and correct copy of the Expert Report of Sonal Singh, MD, MPH, dated November 16, 2018.

13. Attached hereto as Exhibit 11 is a true and correct copy of the Expert Report of Ellen Blair Smith, M.D., dated November 16, 2018.

14. Attached hereto as Exhibit 12 is a true and correct copy of the Expert Report of Daniel Clarke-Pearson, MD, dated November 16, 2018.

15. Attached hereto as Exhibit 13 is a true and correct copy of the Expert Report of Judith Wolf, MD, dated November 16, 2018.

16. Attached hereto as Exhibit 14 is a true and correct copy of the Deposition of Judith Wolf, MD, dated January 7, 2019.

17. Attached hereto as Exhibit 15 is a true and correct copy of the Report of Sarah Kane, MD, dated November 15, 2018.

18. Attached hereto as Exhibit 16 is a true and correct copy of the Expert Report of Laura Plunkett, Ph.D., DABT, dated November 16, 2018 (FILED UNDER SEAL).

19. Attached hereto as Exhibit 17 is a true and correct copy of the Deposition of Laura Plunkett, Ph.D., DABT, dated December 19, 2018.

20. Attached hereto as Exhibit 18 is a true and correct copy of the Report of Arch Carson, MD, Ph.D, dated November 16, 2018.

21. Attached hereto as Exhibit 19 is a true and correct copy of the Deposition Arch Carson, MD, Ph.D., dated January 19, 2019.

22. Attached hereto as Exhibit 20 is a true and correct copy of excerpts from Rothman, et al., *Modern Epidemiology* (3d ed., 2008).

23. Attached hereto as Exhibit 21 is a true and correct copy of Cramer, et al., *Ovarian Cancer and Talc: A Case-Control Study*, 50 *Cancer* 372 (1982).

24. Attached hereto as Exhibit 22 is a true and correct copy of Hartge, et al., *Talc and Ovarian Cancer*, 250 *JAMA* 1844 (1983).

25. Attached hereto as Exhibit 23 is a true and correct copy of Whittemore, et al., *Personal and Environmental Characteristics Related to Epithelial Ovarian Cancer*, 128 *Am. J. Epidemiology* (1988).

26. Attached hereto as Exhibit 24 is a true and correct copy of Harlow, et al., *A Case –Control Study of Borderline Ovarian Tumors: the Influence of Perineal Exposure to Talc*, 130 *Am. J. Epidemiology* 390 (1989).

27. Attached hereto as Exhibit 25 is a true and correct copy of Booth, *Risk Factors for Ovarian Cancer: a Case-Control Study*, 60 *Brit. J. Cancer* 592 (1989).

28. Attached hereto as Exhibit 26 is a true and correct copy of Harlow, et al., *Perineal Exposure to Talc and Ovarian Cancer Risk*, 80 *Obstetrics & Gynecology* 19 (1992).

29. Attached hereto as Exhibit 27 is a true and correct copy of Hartge, et al., *Occupation and Ovarian Cancer: A Case-Control Study in the Washington, DC, Metropolitan Area, 1978-1981*, *J. Occupational Med.* 924 (1994).

30. Attached hereto as Exhibit 28 is a true and correct copy of Rosenblatt, et al., *Mineral Fiber Exposure and the Development of Ovarian Cancer* 45 Gynecologic Oncology 20 (1992).

31. Attached hereto as Exhibit 29 is a true and correct copy of Chen, et al., *Risk Factors for Epithelial Ovarian Cancer in Beijing, China*, 21 Int'l J. Epidemiology 23 (1992).

32. Attached hereto as Exhibit 30 is a true and correct copy of Tzonou, et al., *Hair Dyes, Analgesics, Tranquilizers and Perineal Talc Application as Risk Factors for Ovarian Cancer*, 55 Int'l J. Cancer 408 (1993).

33. Attached hereto as Exhibit 31 is a true and correct copy of Purdie, et al., *Reproductive and Other Factors and Risk of Epithelial Ovarian Cancer: an Australian Case-Control Study*, 62 Int'l J. Cancer 678 (1995).

34. Attached hereto as Exhibit 32 is a true and correct copy of Shushan, et al., *Human Menopausal Gonadotropin and the Risk of Epithelial Ovarian Cancer*, 65 Fertility & Sterility 13 (1996).

35. Attached hereto as Exhibit 33 is a true and correct copy of Green, et al., *Tubal Sterilisation, Hysterectomy and Decreased Risk of Ovarian Cancer*, 71 Int'l J. Cancer 948 (1997).

36. Attached hereto as Exhibit 34 is a true and correct copy of Chang et al., *Perineal Talc Exposure and Risk of Ovarian Carcinoma*, 79 Cancer 2396 (1997).

37. Attached hereto as Exhibit 35 is a true and correct copy of Cook, et al., *Perineal Powder Exposure and the Risk of Ovarian Cancer*, 145 Am. J. Epidemiology 459 (1997).

38. Attached hereto as Exhibit 36 is a true and correct copy of Godard, et al., *Risk Factors for Familial and Sporadic Ovarian Cancer Among French Canadians: a Case-Control Study*, 179 Am. J. Obstetrics & Gynecology 403 (1998).

39. Attached hereto as Exhibit 37 is a true and correct copy of Cramer, et al., *Genital Talc Exposure and Risk of Ovarian Cancer*, 81 Int'l J. Cancer 351 (1999).

40. Attached hereto as Exhibit 38 is a true and correct copy of Wong, et al., *Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: a Case-Control Study*, 93 Obstetrics & Gynecology 372 (1999).

41. Attached hereto as Exhibit 39 is a true and correct copy of Ness, *Factors Related to Inflammation of the Ovarian Epithelium and Risk of Ovarian Cancer*, 11 Epidemiology 111 (2000).

42. Attached hereto as Exhibit 40 is a true and correct copy of Mills, et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, 112 Int'l J. Cancer 458 (2004).

43. Attached hereto as Exhibit 41 is a true and correct copy of Pike, et al., *Hormonal Factors and the Risk of Invasive Ovarian Cancer: a Population-Based Case-Control Study*, 82 Fertility & Sterility 186 (2004).

44. Attached hereto as Exhibit 42 is a true and correct copy of Jordan, et al., *Risk Factors for Benign Serous and Mucinous Epithelial Ovarian Tumors*, 109 Obstetrics & Gynecology 647 (2007).

45. Attached hereto as Exhibit 43 is a true and correct copy of Merritt, et al., *Talcum Powder, Chronic Pelvic Inflammation and NSAIDs in Relation to Risk of Epithelial Ovarian Cancer*, 122 Int'l J. Cancer 170 (2008).

46. Attached hereto as Exhibit 44 is a true and correct copy of Moorman, et al., *Ovarian Cancer Risk Factors in African-American and White Women*, 170 Am. J. Epidemiology 598 (2009).

47. Attached hereto as Exhibit 45 is a true and correct copy of Wu, *Markers of Inflammation and Risk of Ovarian Cancer in Los Angeles County*, 124 Int'l J. Cancer 1409 (2009).

48. Attached hereto as Exhibit 46 is a true and correct copy of Rosenblatt, et al., *Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer*, 22 *Cancer Causes Control* 737 (2011).

49. Attached hereto as Exhibit 47 is a true and correct copy of Kurta, et al., *Use of Fertility Drugs and Risk of Ovarian Cancer: Results from a U.S.-Based Case-Control Study*, 21 *Cancer Epidemiology Biomarkers Prev.* 1282 (2012).

50. Attached hereto as Exhibit 48 is a true and correct copy of Wu, *African-Americans and Hispanics Remain at Lower Risk of Ovarian Cancer than Non-Hispanic Whites After Considering Non-Genetic Risk Factors and Oophorectomy Rates*, 24 *Cancer Epidemiology Biomarkers Prev.* 1094 (2015).

51. Attached hereto as Exhibit 49 is a true and correct copy of Cramer, et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, 27 *Epidemiology* 334 (2016).

52. Attached hereto as Exhibit 50 is a true and correct copy of Terry, et al., *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 85, 25 Cases and 9,859 Controls*, 6 *Cancer Prev. Research* 811 (2013).

53. Attached hereto as Exhibit 51 is a true and correct copy of Gertig, et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 *J. Nat'l Cancer Inst.* 249 (2000).

54. Attached hereto as Exhibit 52 is a true and correct copy of Gates, et al., *Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer*, 17 *Cancer Epidemiology Biomarkers Prev.* 2436 (2008).

55. Attached hereto as Exhibit 53 is a true and correct copy of Gates, et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 *Am. J. Epidemiology* 45 (2010).

56. Attached hereto as Exhibit 54 is a true and correct copy of Houghton, et al., *Perineal Powder Use and Risk of Ovarian Cancer*, 106 *J. Nat'l Cancer Inst.* (2014).

57. Attached hereto as Exhibit 55 is a true and correct copy of Gonzalez, et al., *Douching, Talc Use, and Risk of Ovarian Cancer*, 27 *Epidemiology* 797 (2016).

58. Attached hereto as Exhibit 56 is a true and correct copy of *Draft Screening Assessment – Talc*, Environment and Climate Change Canada, Health Canada, December 2018.

59. Attached hereto as Exhibit 57 is a true and correct copy of excerpts from IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 93: *Carbon Black, Titanium Dioxide and Talc*, 2010.

60. Attached hereto as Exhibit 58 is a true and correct copy of Rothman, K.J., *Six Persistent Research Misconceptions*, 29 J. Gen. Internal Med. 1060 (2014).

61. Attached hereto as Exhibit 59 is a true and correct copy of the Deposition of Anne McTiernan, MD, Ph.D., dated January 28, 2019.

62. Attached hereto as Exhibit 60 is a true and correct copy of excerpts from Borenstein, et al., *Introduction to Meta-Analysis* (2009).

63. Attached hereto as Exhibit 61 is a true and correct copy of Berge, et al., *Genital Use of Talc and Risk of Ovarian cancer: a Meta-Analysis*, 27 European J. Cancer Prev. 248 (2018).

64. Attached hereto as Exhibit 62 is a true and correct copy of Penninkilampi, et al., *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29 Epidemiology 41 (2018).

65. Attached hereto as Exhibit 63 is a true and correct copy of Taher, et al., *Systematic Review and Meta-Analysis of the Association Between perineal Use of talc and Risk of Ovarian Cancer*, Unpublished Manuscript (2018).

66. Attached hereto as Exhibit 64 is a true and correct copy of the Deposition of Rebecca Smith-Bindman, MD, dated February 7, 2019 and February 8, 2019.

67. Attached hereto as Exhibit 65 is a true and correct copy of Jones & Lopez, *Human Reproductive Biology, Chapter 9: Gamete Transport and Fertilization* (4th ed. 2006).

68. Attached hereto as Exhibit 66 is a true and correct copy of Kissler, et al., *Uterine contractility and directed sperm transport assessed by hysterosalpingoscintigraphy (HSSG) and intrauterine pressure (IUP) measurement*, 83 Acta Obstet Gynecol Scand 369-374 (2004).

69. Attached hereto as Exhibit 67 is a true and correct copy of Egli and Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12 Fertility and Sterility 151-155 (1961).

70. Attached hereto as Exhibit 68 is a true and correct copy of Blumenkrantz, et al., *Retrograde Menstruation in Women Undergoing Chronic Peritoneal Dialysis*, 57 Obstetrics and Gynecology 667-70 (1981).

71. Attached hereto as Exhibit 69 is a true and correct copy of Halme, et al., *Retrograde Menstruation in Healthy Women and in Patients with Endometriosis*, 64 Obstetrics and Gynecology 151-54 (1984).

72. Attached hereto as Exhibit 70 is a true and correct copy of Venter and Iturralde, *Migration of a Particulate Radioactive Tracer from the Vagina to the Peritoneal Cavity and Ovaries*, 55 S. Afr. Med. J. 917-19 (1979).

73. Attached hereto as Exhibit 71 is a true and correct copy of Kunz, et al., *The Uterine Peristaltic Pump. Normal and Impeded Sperm Transport within the Female Genital Tract*, 424 *Advances in Experimental Medicine and Biology* 267-77 (1997).

74. Attached hereto as Exhibit 72 is a true and correct copy of Zervomanoklakis, et al., *Physiology of Upward Transport in the Human Female Genital Tract*, 1101 *Annals of New York Academy of Sciences* 1-20 (2007).

75. Attached hereto as Exhibit 73 is a true and correct copy of Sjosten, et al., *Retrograde Migration of Glove Powder in the Human Female Genital Tract*, 19 *Human Reproduction* 991-95 (2004).

76. Attached hereto as Exhibit 74 is a true and correct copy of Henderson, et al., *Talc and Carcinoma of the Ovary and Cervix*, 78 *Brit. Obstetrics and Gynaecology* 266-72 (1971).

77. Attached hereto as Exhibit 75 is a true and correct copy of Heller, et al., *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, 174 *Am. J. Obstetrics & Gynecology* 1507-10 (1996).

78. Attached hereto as Exhibit 76 is a true and correct copy of Cramer, et al., *Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110 *Obstetrics & Gynecology* 498-501 (2007).

79. Attached hereto as Exhibit 77 is a true and correct copy of McDonald, et al., *Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes*, Ultrastructural Pathology (2019).

80. Attached hereto as Exhibit 78 is a true and correct copy of the Letter from Steven Musser (FDA) to Samuel S. Epstein, M.D., dated April 1, 2014.

81. Attached hereto as Exhibit 79 is a true and correct copy of the Deposition of Sonal Singh, MD, MPH, dated January 16, 2019.

82. Attached hereto as Exhibit 80 is a true and correct copy of excerpts from IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, *Arsenic, Metals, Fibres, and Dusts*, Vol. 100C: A review of Human Carcinogens, 2012.

83. Attached hereto as Exhibit 81 is a true and correct copy of Eberl, et al., *Comparative Evaluation of the Effects of Talcum and a New Absorbable Substitute on Surgical Gloves*, 75 Am. J. Surgery 493 (1948).

84. Attached hereto as Exhibit 82 is a true and correct copy of 81 Fed. Reg. 91723 (codified at 21 C.F.R. pts. 878, 880, & 895), *Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove* (December 19, 2016).

85. Attached hereto as Exhibit 83 is a true and correct copy of Geonofre, et al., *Inflammation and Clinical Repercussions of Pleurodesis Induced by Intrapleural Talc Administration*, 62 Clinics (Sao Paulo) 627 (2007).

86. Attached hereto as Exhibit 84 is a true and correct copy of Ghio, et al., *Talc Should Not be Used for Pleurodesis in Patients with Nonmalignant Pleural Effusions*, 164 Am. J. Respiratory & Critical Care Medicine 1471 (2001).

87. Attached hereto as Exhibit 85 is a true and correct copy of Mostafa, et al., *Foreign Body Granulomas in Normal Ovaries*, 66 Obstetrics and Gynecology 701-2 (1985).

88. Attached hereto as Exhibit 86 is a true and correct copy of Vanderhyden, et al., *Animal Models of Ovarian Cancer*, 1 Reproductive Biology & Endocrinology 67 (2003).

89. Attached hereto as Exhibit 87 is a true and correct copy of Graham & Jenkins, *Value of modified Starch as a Substitute for Talc*, 1 Lancet 590-91 (1952).

90. Attached hereto as Exhibit 88 is a true and correct copy of National Toxicology Program, *NTP Technical Report on the Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96-6) (NonAsbestiform) in F344/N Rats and B6C3F1 Mice (Inhalation Studies)* (1993).

91. Attached hereto as Exhibit 89 is a true and correct copy of Graham & Graham, *Ovarian Cancer and Asbestos*, 1 Environmental Research 115-28 (1967).

92. Attached hereto as Exhibit 90 is a true and correct copy of Hamilton, et al., *Effects of Talc on the Rat Ovary*, 65 Br. J. Experimental Pathology 101-6 (1984).

93. Attached hereto as Exhibit 91 is a true and correct copy of Keskin, et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital System of Rats? An Experimental Pilot Study*, 280 Archives Gynecology & Obstetrics 925-31 (2009).

94. Attached hereto as Exhibit 92 is a true and correct copy of Moller & Jantzen, *Oxidatively Damaged DNA in Animals Exposed to Particles*, 43 Critical Reviews in Toxicology 96-118 (2013).

95. Attached hereto as Exhibit 93 is a true and correct copy of Shukla, et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41 Am. Respiratory Cell & Molecular Biology 114-23 (2009).

96. Attached hereto as Exhibit 94 is a true and correct copy of Buz'Zard & Lau, *Pycnogenol Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures*, 21 Phytother. Res. 579 (2007).

97. Attached hereto as Exhibit 95 is a true and correct copy of Akhtar, et al., *Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two*

Different Geographical Regions in Human Lung Epithelial Cells, *Envtl. Tox.* 394-404 (2014).

98. Attached hereto as Exhibit 96 is a true and correct copy of Akhtar, et al., *The Primary Role of Iron-Mediated Lipid Peroxidation in the Differential Cytotoxicity Caused by Two Varieties of Talc Nanoparticles on A549 Cells and Lipid Peroxidation Inhibitory Effect Exerted by Ascorbic Acid*, 24 *Tox. In Vitro* 1139-47 (2010).

99. Attached hereto as Exhibit 97 is a true and correct copy of Fletcher, et al., *Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer*, 20 *Reproductive Sciences* 1 (2019).

100. Attached hereto as Exhibit 98 is a true and correct copy of Balkwill & Mantovani, *Inflammation and Cancer: Back to Virchow?*, 357 *Lancet* 539 (2001).

101. Attached hereto as Exhibit 99 is a true and correct copy of Hanahan & Weinberg, *Hallmarks of Cancer: The Next Generation*, 144 *Cell* 646 (2011).

102. Attached hereto as Exhibit 100 is a true and correct copy of Coussens & Webb, *Inflammation and Cancer*, 420 *Nature* 860-67 (2002).

103. Attached hereto as Exhibit 101 is a true and correct copy of Liou & Storz, *Reactive oxygen species in cancer*, 44 *Free Radical Research* 479-96 (2010).

104. Attached hereto as Exhibit 102 is a true and correct copy of Grivennikov, et al., *Immunity, inflammation, and cancer*, 140 *Cell* 883 (2010).

105. Attached hereto as Exhibit 103 is a true and correct copy of Reuter, et al., *Oxidative stress, inflammation, and cancer: How are they linked?*, 49 Free Radical Biol. Med 1603-1616 (2011).

106. Attached hereto as Exhibit 104 is a true and correct copy of Fernandes, et al., *The Role of Mediators of Inflammation in Cancer Development*, 21 Pathol. Oncol. Res. 527-34 (2015)

107. Attached hereto as Exhibit 105 is a true and correct copy of Kiraly, et al., *Inflammation, DNA Damage and Mutations In Vivo*, 11 PLO Genetics 1-24 (2015).

108. Attached hereto as Exhibit 106 is a true and correct copy of Ness & Cottreau, *Possible Role of Ovarian Epithelial Inflammation in Ovarian Cancer*, 91 J. Nat'l Cancer Inst. 1459-63 (1999).

109. Attached hereto as Exhibit 107 is a true and correct copy of September 30, 2004 Faxed document from Richard Zazenski, Director Product Safety to Bill Ashton (Bates JNJ 000000704 - JNJ 000000709).

110. Attached hereto as Exhibit 108 is a true and correct copy of Freedman, et al., *Peritoneal inflammation – A microenvironment for Epithelial Ovarian Cancer (EOC)*, 2 J. Translational Med. 1-10 (2004).

111. Attached hereto as Exhibit 109 is a true and correct copy of Shan & Liu, *Inflammation: A hidden path to breaking the spell on ovarian cancer*, 8 Cell Cycle 3107-3111 (2009).

112. Attached hereto as Exhibit 110 is a true and correct copy of Trabert, et al., *Pre-diagnostic levels of inflammation markers and risk of ovarian cancer in the Prostate, Lung, Colorectal and Ovarian Cancer (PLCO) Screening Trial*, 135 Gynecologic Oncology 297-304 (2014).

113. Attached hereto as Exhibit 111 is a true and correct copy of Rasmussen, et al., *Pelvic Inflammatory Disease and the Risk of Ovarian Cancer and Borderline Tumors: A Pooled Analysis of 12 Case-Control Studies*, 185 Am. J. Epidemiology 8-20 (2017).

114. Attached hereto as Exhibit 112 is a true and correct copy of National Academies of Science, Engineering and Medicine, *Ovarian Cancers: Evolving Paradigms in Research and Care* (2016).

115. Attached hereto as Exhibit 113 is a true and correct copy of Saed, et al., *Updates on the role of oxidative stress in the pathogenesis of ovarian cancer*, 145 Gynecologic Oncology 595-602 (2017).

116. Attached hereto as Exhibit 114 is a true and correct copy of the Deposition of Michael Birrer, MD, PhD, dated March 29, 2019.

117. Attached hereto as Exhibit 115 is a true and correct copy of Savant, et al., *The role of inflammation and inflammatory mediators in the development, progression, metastasis, and chemoresistance of epithelial ovarian cancer*, 10 Cancers 1-30 (2018).

118. Attached hereto as Exhibit 116 is a true and correct copy of Mossman, *Mechanistic in vitro studies: What they have told us about carcinogenic properties of elongated mineral particles (EMPs)*, 361 Tox. & Applied Pharmac. 62-67 (2018).

119. Attached hereto as Exhibit 117 is a true and correct copy of US Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Nickel* (2005).

120. Attached hereto as Exhibit 118 is a true and correct copy of excerpts from US Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Chromium* (2012).

121. Attached hereto as Exhibit 119 is a true and correct copy of US Department of Health and Human Services, National Toxicology Program, *Report on Carcinogens: Monograph on Cobalt and Cobalt Compounds that Release Cobalt Ions in vivo* (2016).

122. Attached hereto as Exhibit 120 is a true and correct copy of excerpts from Brewster, *Epidemiology of commonly used statistical terms and analysis of clinical studies*, Clinical Gynecologic Oncology (9th ed. 2017).

123. Attached hereto as Exhibit 121 is a true and correct copy of the Deposition of Daniel Clarke-Pearson, MD, dated February 4, 2019.

124. Attached hereto as Exhibit 122 is a true and correct copy of Vineis et al., *Causality in cancer research: A journey through models in molecular epidemiology and their philosophical interpretation*, 14 Emerging Themes in Epidemiology 7 (2017).

125. Attached hereto as Exhibit 123 is a true and correct copy of Wu, et al., *Evaluating intrinsic and non-intrinsic cancer risk factors*, 9 Nature Commc'n 3490 (2018).

126. Attached hereto as Exhibit 124 is a true and correct copy of Hunn & Rodriguez, *Ovarian Cancer: Etiology, Risk Factors, and Epidemiology*, 55 Clin Obstet Gynecology 3-23 (2012).

127. Attached hereto as Exhibit 125 is a true and correct copy of Mallen, et al., *Risk Factors for Ovarian Carcinoma*, Hematol Oncol Clin N Am 1-12 (2018).

128. Attached hereto as Exhibit 126 is a true and correct copy of Park, et al., *Benign gynecologic conditions are associated with ovarian cancer risk in African-American women: a case-control study*, Cancer Causes & Control (2018).

129. Attached hereto as Exhibit 127 is a true and correct copy of excerpts from Eeles, et al. *Cancer Prevention and Screening: Concepts, Principles and Controversies*, Chapter 23 (2018).

130. Attached hereto as Exhibit 128 is a true and correct copy of Lheureux, et al., *Epithelial ovarian cancer*, 393 *Lancet* 1240-53 (2019).

131. Attached hereto as Exhibit 129 is a true and correct copy of Morice, et al., *Mucinous Ovarian Cancer*, 380 *New Eng. J. Med.* 1256 (2019).

132. Attached hereto as Exhibit 130 is a true and correct copy of the Memorandum Opinion and Order, *Deane Berg v. Johnson & Johnson*, et al., Case No. 4:09-cv-04179-KES, (D.S.D), April 12, 2013.

133. Attached hereto as Exhibit 131 is a true and correct copy of the Order, *Blaes v. Johnson & Johnson*, 1422-CC0936-10, June 12, 2017.

134. Attached hereto as Exhibit 132 is a true and correct copy of the Order, *Brower v. Johnson & Johnson*, No. 16-EV---5534-E (Ga. Fulton Co.), March 26, 2019.

135. Attached hereto as Exhibit 133 is a true and correct copy of excerpts from Gordis, *Epidemiology* (5th ed. 2013).

136. Attached hereto as Exhibit 134 is a true and correct copy of the Deposition of Linda Loretz, Ph.D., dated October 1, 2018.

137. Attached hereto as Exhibit 135 is a true and correct copy of May 8, 2009 FDA Meeting Minutes, Exhibit 56 from the Deposition of Linda Loretz, Ph.D., dated October 1, 2018.

138. Attached hereto as Exhibit 136 is a true and correct copy of Narod, *Talc and Ovarian Cancer*, 141 *Gynecologic Oncology* 410 (2016).

139. Attached hereto as Exhibit 137 is a true and correct copy of Wasserstein, et al., *Moving to a World Beyond “ $p < .05$ ”*, 73 *The American Statistician* 1 (Supp. 1 2019).

140. Attached hereto as Exhibit 138 is a true and correct copy of Amrhein, et al., *Retire Statistical Significance*, 567 *Nature* 305 (2019).

141. Attached hereto as Exhibit 139 is a true and correct copy of the Deposition of Sarah Kane, MD, dated January 25, 2019.

142. Attached hereto as Exhibit 140 is a true and correct copy of the curriculum vitae of Karla Ballman, PhD.

143. Attached hereto as Exhibit 141 is a true and correct copy of the Deposition of Gregory Diette, MD, MHS, dated April 9, 2019.

144. Attached hereto as Exhibit 142 is a true and correct copy of Wassertein et al., *The ASA’s Statement on p-Values: Context, Process, and Purpose*, 70 *The American Statistician* 129 (2016).

145. Attached hereto as Exhibit 143 is a true and correct copy of excerpts from Oleckno, *Epidemiology: Concepts and Methods* (2008).

146. Attached hereto as Exhibit 144 is a true and correct copy of the Deposition of Ellen Blair Smith, MD, dated January 9, 2019.

147. Attached hereto as Exhibit 145 is a true and correct copy of the Deposition of Jack Siemiatycki, MSc, PhD, dated January 31, 2019.

148. Attached hereto as Exhibit 146 is a true and correct copy of Rothman, et al. *Interpretation of Epidemiologic Studies on Talc and Ovarian Cancer* (Nov. 28, 2000), IMERYYS 209695.

149. Attached hereto as Exhibit 147 is a true and correct copy of the Report of Karla Ballman, PhD, dated February 25, 2019.

150. Attached hereto as Exhibit 148 is a true and correct copy of the Report of Christian Merlo, MD, PhD, dated February 25, 2019.

151. Attached hereto as Exhibit 149 is a true and correct copy of the Report of Gregory Diette, MD, MHS, dated February 25, 2019.

152. Attached hereto as Exhibit 150 is a true and correct copy of National Cancer Institute, *Ovarian, Fallopian Tube and Primary Peritoneal Cancer Prevention (PDQ®)-Health Professional Version*, dated March 15, 2019.

153. Attached hereto as Exhibit 151 is a true and correct copy of Affidavit of Patricia Gripka Moorman, M.S.P.H., Ph.D., dated May 21, 2018.

154. Attached hereto as Exhibit 152 is a true and correct copy of 70 Fed. Reg. 60548, *National Toxicology Program (NTP); Report on Carcinogens; Status of Nominations to the 12th Report on Carcinogens (RoC): Request for Comments and Nominations of Scientific Experts* (October 18, 2005).

155. Attached hereto as Exhibit 153 is a true and correct copy of Hothorn, et al., *Trend tests for the evaluation of exposure-response relationships in epidemiological exposure studies*, 6 Epidemiologic Perspectives & Innovations 1 (2009).

156. Attached hereto as Exhibit 154 is a true and correct copy of Greenland, *Dose-Response and trend analysis in epidemiology: Alternatives to categorical analysis*, 6 Epidemiology 356-65 (1995).

157. Attached hereto as Exhibit 155 is a true and correct copy of Huncharek & Muscat, *Perineal talc use and ovarian cancer risk: a case study of scientific standards in environmental epidemiology*, 20 Eur. J. Cancer Prevention 501 (2011).

158. Attached hereto as Exhibit 156 is a true and correct copy of Exhibit 25 from the Deposition of Joshua Muscat, PhD, dated September 25, 2018 – July 21, 2009 *Comments on: Citizens Petition to the Commissioner of the Food and Drug Administration Seeking a Cancer Warning on Talc Products* submitted by Personal Care Products Council.

159. Attached hereto as Exhibit 157 is a true and correct copy of Deposition of Joshua Muscat, PhD, dated September 25, 2018.

160. Attached hereto as Exhibit 158 is a true and correct copy of the Deposition of Robert Glenn, dated October 18, 2018.

161. Attached hereto as Exhibit 159 is a true and correct copy of Huncharek, et al., *Use of Cosmetic Talc on Contraceptive Diaphragms and Risk of Ovarian Cancer: a Meta-Analysis of Nine Observational Studies*, 16 Eur. J. Cancer Prev. 422 (2007).

162. Attached hereto as Exhibit 160 is a true and correct copy of excerpts from IARC Monographs on the Evaluation of Carcinogenic Risks of Chemicals to Humans, Vol. 42: *Silica and Some Silicates*, (1987).

163. Attached hereto as Exhibit 161 is a true and correct copy of Fedak, et al., *Applying the Bradford Hill criteria in the 21st Century: How data integration has changed causal inference in molecular epidemiology*, 12 Emerging Themes in Epidemiology 14 (2015).

164. Attached hereto as Exhibit 162 is a true and correct copy of Tao, et al., *Weight of Evidence: General Principles and Current Applications at Health Canada*, Health Canada (2018).

165. Attached hereto as Exhibit 163 is a true and correct copy of Purdie, et al., *Ovulation and risk of epithelial ovarian cancer*, 104 Int'l. J. Cancer 228 (2003).

166. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I may be subject to punishment.

Dated: May 29, 2019

/s/ Michelle A. Parfitt
Michelle A. Parfitt